

REMARKS

Claims 16-31 are pending. By this amendment, the specification and claims 16, 22, 25 and 27 are amended and claims 29-31 are added. No new matter is added. In view of the foregoing amendments and following remarks, reconsideration and withdrawal of the outstanding rejections are respectfully requested.

Applicants appreciate the courtesies shown to Applicants' representatives by Examiner Berch in the September 11, 2003 personal interview. Applicants' separate record of the substance of the interview is incorporated into the following remarks.

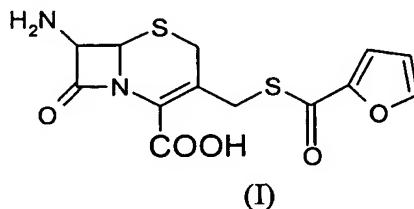
The specification and claims 16, 22, 25 and 27 are amended to add the prefix "7-amino-" to each iteration of the phrase "3-[2-(furylcarbonyl) thiomethyl]-3-cephem-4-carboxylic acid." The omission of the "7-amino-" prefix from "7-amino-3-[2-(furylcarbonyl) thiomethyl]-3-cephem-4-carboxylic acid" is the result of an editorial error, and support for the corrective amendments can be found, for example, at page 1, lines 4-9 of the instant specification, which provides the correct name of the compound and refers to a structural rendering clearly showing an amino group at the "7" position of the compound.

The above-described editorial error was carried into Applicants' Rule 608(b) Showing and the Declarations in support of that Showing. However, the presence of the error in the Rule 608(b) Showing and Declarations does not diminish the force of the assertions included therein. In the Rule 608(b) Showing and in each of the Declarations in which the term "3-[2-(furylcarbonyl) thiomethyl]-3-cephem-4-carboxylic acid" is used, reference is made to the interchangeability of the term "3-[2-(furylcarbonyl) thiomethyl]-3-cephem-4-carboxylic acid" with the term "furaca" and a structural rendering of the formula. The intent of Applicants and the Declarants would be readily appreciated by one of ordinary skill in the art, as it is well known that "furaca" is "7-amino-3-[2-(furylcarbonyl) thiomethyl]-3-cephem-4-carboxylic acid," as stated in the present specification. Moreover, the structural renderings of the

pertinent formula in the Rule 608(b) Showing and the relevant Declarations clearly show an amino group in the "7" position of the depicted compound.

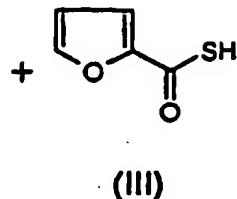
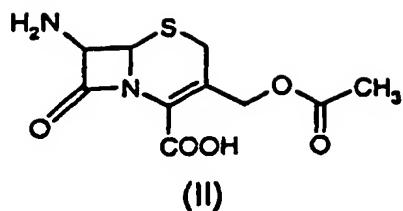
While the above-described error may be benign, Applicants would prefer that it not persist in these proceedings. Accordingly, Applicants submit that claim 16, as amended herein, should be the Count of the interference requested by Applicants on January 16, 2003. The proposed Count would thus recite:

A process to prepare a cephalosporin compound (Furaca: 7-amino-3-[2-(furylcarbonyl) thiomethyl]-3-cephem-4-carboxylic acid) represented by formula (I),



comprising:

- (a) combining the following components:
  - (i) a catalyst solution of boron trifluoride in an organic solvent or in a mixture of organic solvents,
  - (ii) a solution of 2-thiofuroic acid (furyl-2-carbonylthiol) of the formula (III) in a solvent, and
  - (iii) 7-aminocephalosporanic acid of the formula (II), and
- (b) precipitating Furaca (7-amino-3-[2-(furylcarbonyl) thiomethyl]-3-cephem-4-carboxylic acid) as a solid.



This amendment to the proposed Count does not affect the correspondence of the amended application claims or the U. Kumar et al. claims to the Count, because it has no effect on the scope of the claims or the Count. In particular, "7-amino-3-[2-(furylcarbonyl)thiomethyl]-3-cephem-4-carboxylic acid," or "furaca," is the compound recited in the claims and the Count both before and after the above amendments. This compound is also shown structurally in the claims and the Count. Accordingly, the grounds upon which Applicants have requested an interference between present claims 16-28 and claims 1-3 of the U. Kumar et al. patent remain unchanged.

Claims 29-31 are added in response to Examiner Berch's suggestions during the September 11 personal interview. New claim 29 is similar to claim 16, but paragraph (a)(ii) does not include the requirement that 2-thiofuroic acid be provided in solution. New claim 30 depends from claim 29, and provides that the 2-thiofuroic acid is provided in an organic solvent. New claim 31 corresponds to new claim 29, but further includes a temperature limitation. As agreed during the personal interview and reflected in the Interview Summary, each of these claims is adequately supported as to their respective 2-thiofuroic acid features. While Applicants submit that each of the pending claims is adequately supported in its entirety, claim 31 further recites "at a reaction temperature between 20°C and 50°C," and thus render moot all outstanding grounds for rejection.

New claims 29-31 each correspond substantially to the proposed Count. New claim 29 includes each of the features of claim 16, except it does not recite that 2-thiofuroic acid is "in a solvent." The recitation of "2-thiofuroic acid ... in a solvent" in the Count anticipates the recitation of 2-thiofuroic acid in claim 29, and likewise adding, "2-thiofuroic acid ... in a solvent" is an obvious way to add 2-thiofuroic acid, as evidenced by the ubiquitous presence of 2-thiofuroic acid in an organic solvent in the Examples of the U. Kumar et al. patent and the instant specification. Accordingly, the 2-thiofuroic acid feature of claim 29 corresponds substantially to the "2-thiofuroic acid ... in a solvent" of the Count, and the remaining features of claim 29 correspond exactly to the remaining features of the Count for reasons previously provided with respect to claim 16. New claim 30 depends from claim 29, and recites that 2-thiofuroic acid is "in an organic solvent." The recitation of "2-thiofuroic acid in an organic solvent" in claim 30 anticipates the recitation of "2-thiofuroic acid ... in a solvent" in the Count, and likewise, "2-thiofuroic acid in an organic solvent" is an obvious variant of "2-thiofuroic acid ... in a solvent," as evidenced, again, by the Examples of the U. Kumar et al. patent and the instant specification. Accordingly, the "2-thiofuroic acid in an organic solvent" of claim 30 corresponds substantially to the "2-thiofuroic acid ... in a solvent" of the Count, and the remaining features of claim 30 correspond exactly to remaining features of the Count for reasons provided with respect to claim 16.

New claim 31 includes each of the features of claim 25, except that it does not recite that the 2-thiofuroic acid is provided "in an organic solvent." Claim 25 also does not recite "2-thiofuroic acid ... in a solvent" as in the Count. As explained with respect to claim 29, the recitation of 2-thiofuroic acid in claim 30 corresponds substantially to the recitation of feature "2-thiofuroic acid ... in a solvent" in the Count. The remaining features of claim 30 correspond substantially to the remaining features of the Count for the reasons provided with

respect to claim 25. For at least these reasons, claims 29-31 each correspond substantially to the proposed Count.

The terms of claims 29-31 are supported in Applicants' disclosure, for example, at page 3, line 22-page 4, line 11, page 5, lines 3-8 and 12-15, and the Examples. Each of the pending claims was presented less than one year after issuance of the U. Kumar et al. patent (November 5, 2002).

With respect to the outstanding rejection of claims 16-20 and 22-24 under the written description requirement of 35 U.S.C. §112, first paragraph for not reciting a temperature limitation and/or for not reciting "organic" as a modifier of the term "solvent" for the 2-thiofuroic acid solution, Applicants provide the following additional comments.

Applicants submit that claim 16, as written, meets the written description requirement of 35 U.S.C. §112, first paragraph. Pertinent to the outstanding rejections, claim 16 does not recite a temperature limitation and recites "a solution of 2-thiofuroic acid (furyl-2-carbonylthiol) of the formula (III) in a solvent." Both of these aspects of claim 16 are well-supported in the instant specification.

The scope of Applicants' invention is described at the very beginning of the instant specification. The specification states: "[t]he present invention discloses an improved process for the preparation of 7-amino-3-[2-(furylcarbonyl) thiomethyl]-3-cephem-4-carboxylic acid represented by formula (I) by the condensation of 7-aminocephalosporanic acid (7-ACA) represented by formula (II) with furyl-2-carbonylthiol represented by formula (III) using borontrifluoride as condensing agent." Instant specification at page 1, lines 1-6. At page 3, lines 5-8, the specification states: "[i]n order to overcome this problem, the applicant provides for the first time an improved process for condensing 7-ACA with furyl-2-carbonylthiol which is generated and used in situ in the presence of boron trifluoride in a gaseous state or its solution in an organic solvent to obtain [the] compound of formula (I)."

Conspicuously absent from these passages is any requirement that the process be carried out at any particular temperature or any requirement that the 2-thiofuroic acid (furyl-2-carbonylthiol) be provided in an organic solvent. While the specification certainly describes that the reaction can be carried out at particular temperatures and that the 2-thiofuroic acid can be provided in an organic solvent, these are embodiments of the invention. Nowhere do Applicants convey that either a temperature limitation or an organic solvent limitation is critical or essential to the invention. Rather, it is plain from the above-quoted passage that Applicants envisioned a process that was not limited to a particular reaction temperature or a particular form of 2-thiofuroic acid solution.

With respect to the limitation "in a solvent," as relates to 2-thiofuroic acid, Applicants clearly envisioned that 2-thiofuroic acid could be used in a solvent. As noted in the passages quoted above, Applicants did not intend that 2-thiofuroic acid be limited to any particular form of solvent. It is clear from the instant specification and the original claims of the application that the use of 2-thiofuroic acid in an organic solvent is merely "an embodiment" or subset of the envisioned states of 2-thiofuroic acid. *See* instant specification at page 5, lines 3-4 ("One embodiment of the present invention provides use of furyl-2-carbonylthiol *in situ* as a solution in an organic solvent" (emphasis added)); original claim 1 (which does not specify any solvent for the furyl-2-carbonylthiol of formula (III)). Further, in describing the objects of the invention, Applicants state "[a]nother object of the invention is to use furyl-2-carbonyl thiol [2-thiofuroic acid] *in situ* without isolating it." Instant specification, page 3, lines 14-15. This language does not impose any particular limitation on the state of the 2-thiofuroic acid. Indeed, in the September 11 Interview Summary, Examiner Berch indicates that a claim could meet the written description requirement of 35 U.S.C. §112, first paragraph without reciting a solvent for the 2-thiofuroic acid at all (*see, e.g.*, claims 29 and 31). It is

readily apparent from the instant specification that Applicants envisioned use of 2-thiofuroic acid "in a solvent."

While applicants submit that a claim such as claim 16 is well-supported by the instant specification, any argument that such a claim in any way lacks support can also be made as to the claims of the U. Kumar et al. patent. It is apparent from the specification of the U. Kumar et al. patent that the inventors never disclosed any more specifically than did the present Applicants that the disclosed process be carried out at any temperature other than the disclosed range of 10-50°C. For example, the passage at column 2, line 65 to column 3, line 5 of the U. Kumar et al. patent states: "[i]n accordance with the present invention, there is provided a new process for producing Furaca ... As a rule, boron trifluoride is used in molar excess ... The reaction is effected in ethyl acetate in the temperature range of 10° C. to 50° C., preferably between 30° C. to 35° C." (emphasis added). The only contemplated "embodiment" is the narrower temperature range of 30-35°C.

With respect to the recitation of "2-Thiofuroic Acid ... in a solvent" as recited in claim 1 of the U. Kumar et al. patent, this notion is supported nowhere in the specification and claims of the underlying application as filed. The only support in the U. Kumar et al. patent for "2-Thiofuroic Acid ... in a solvent" are found in the Patent Abstract and in the claims themselves, neither of which appeared in their present forms in the application as filed. The original Abstract makes no reference to 2-thiofuroic acid. The original claims refer to the use of 2-thiofuroic acid "in the presence of boron trifluoride in a solvent or mixture of solvents." This language says nothing about the state of the 2-thiofuroic acid that is added to the disclosed reaction, and by looking at the specification to determine the form in which 2-thiofuroic acid is provided, it is plain that 2-thiofuroic acid is always in an organic solvent in the disclosed embodiments.

While, again, Applicants do not believe that the instant application presents written description issues, it is clear that substantially identical grounds for rejection could be applied to the U. Kumar et al. patent if they are applicable to the present claims. Accordingly, if this rejection is to be maintained, approval of the Technical Center Director is required.

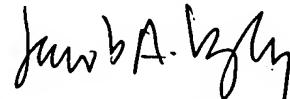
For at least these reasons, Applicants submit that each of the pending claims meets the written description requirement of 35 U.S.C. §112, first paragraph. Accordingly, reconsideration and withdrawal of the outstanding rejections are respectfully requested.

As discussed during the September 11 interview, Applicants have filed herewith an Information Disclosure Statement citing references identified in a proceeding in India.

In view of the above amendments and remarks, and the Showing under Rule 608(b) attached to Applicants' August 14 Amendment, it is respectfully submitted that this application is in condition for allowance and declaration of an interference. Thus, reconsideration and withdrawal of all of the rejections, and indication of allowability of claims 16-31, are respectfully requested. Furthermore, it is respectfully requested that an interference be declared with the Kumar et al. patent, in which present claim 16 is the count of the interference, and with claims 16-31 of the present application and claims 1-3 of the Kumar et al. patent designated to correspond to the Count.

Should there be any questions concerning this matter, please telephone the undersigned at the number set forth below.

Respectfully submitted,



William P. Berridge  
Registration No. 30,024

Jacob A. Doughty  
Registration No. 46,671

WPB:JAD/hs

Date: September 25, 2003 ---

**OLIFF & BERRIDGE, PLC**  
**P.O. Box 19928**  
**Alexandria, Virginia 22320**  
**Telephone: (703) 836-6400**

DEPOSIT ACCOUNT USE  
AUTHORIZATION  
Please grant any extension  
necessary for entry;  
Charge any fee due to our  
Deposit Account No. 15-0461